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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,263	01/27/2004	Claus Meese	55647-C (45107)	3433
21874	7590	09/28/2004		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER TUCKER, ZACHARY C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,263	Applicant(s) MEESE ET AL.	
	Examiner Zachary C. Tucker	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 18-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/700,094.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12Apr04</u> . | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 28, 29, 31, 32, 36, 37, 39, 41-43 and 46-49 (all in part), drawn to compounds of formulae (I), (VII) and (VII'), wherein both of or one of R and R' is alkyl, cycloalkyl or benzyl, the other one of R and R' being hydrogen when both are not as defined as in this Group, classified in class/subclass 564/316 (aromatic amines with an ether function), a process for making the compounds, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- II. Claims 28, 29, 31, 33, 34, 36-39 and 44-49 (all in part), drawn to carbonate compounds of formulae (I), (VI), (VII), (VII') and (VIII) wherein both of or one of R and R' is alkoxycarbonyl, aryloxy carbonyl or benzoyl carbonyl, the other one of R and R' being hydrogen when both are not as defined as in this Group, classified in class/subclass 558/269 (compounds with two carbonate groups), 558/275 (when only R is a carbonate group), 558/276 (when only R' is a carbonate group), a process for making the compounds, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- III. Claims 28, 29, 32, 35, 36, 37, 39, 46, 47 and 49 (all in part) drawn to compounds of formulae (I) and (VII), wherein both of R and R' or one of R and R' are a carbohydrate, classified in class 536 (different subclasses

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depending on the identity of the carbohydrate moiety), pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.

- IV. Claims 28, 29, 30, 35, 36, 37, 38, 39 and 46-49 (all in part) drawn to compounds of formulae (I), (VII) and (VII') wherein both of R and R' or one of R and R' are benzoylglycyl or a substituted amino acid residue, classified in class/subclasses depending on the identity of the amino acid residue, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- V. Claims 28, 29, 33, 34, 36, 37, 39 and 44-49 (all in part), drawn to compounds of formulae (I), (VI), (VII), (VII') and (VIII), wherein both of R and R' or one of R and R' are $C(O)NR^4R^5$ (carbamate esters) classified in class/subclasses 560/32 (when R^4 or R^5 is aryl) and in 560/132 (when both of R^4 and R^5 are acyclic), process for making the compounds, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- VI. Claims 28, 29, 36, 37, 39 and 46-49 (all in part), drawn to compounds of formulae (I) and (VII'), wherein both of R and R' or one of R and R' are $S(O)_2NR^6R^7$ (sulfamate esters) classified in class/subclass 558/48, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.

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- VII. Claims 28, 29, 35, 36, 37, 39, 46-49 (all in part) drawn to compounds of formulae (I) and (VII') wherein both of R and R' or one of R and R' are esters of inorganic acids, classified according to the identity of the esterifying inorganic acid, for example, class/subclass 558/207 (phosphate esters), 558/286 (borate esters), 558/20 (sulfate esters) pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- VIII. Claims 28, 29, 31, 32, 36, 37, 39, 41 and 46-49 (all in part) drawn to compounds of formulae (I), (VI) and (VII') wherein both of R and R' or one of R and R' are a silanyl group $-\text{SiR}_a\text{R}_b\text{R}_c$, classified in class/subclass 556/465, pharmaceutical compositions comprising the compounds and methods of treatment with the compounds.
- IX. Claims 28, 29, 32, 33, 34, 36, 37, 38, 39 and 46-49 (all in part) drawn to compounds according to formulae (I), (VII) and (VII') wherein one of R and R' is a different functional group from Groups I-VIII hereinabove than the other one of R and R' – mixed compounds. These compounds are variously classified, according to the combination of functional groups. Further restriction could be required if this group is elected.
- X. Claim 30 (in part), the second through fifth compounds named in the claim, classified in class 560. These compounds have been patented in US 6,713,464, the parent case of the instant application.

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XI. Claim 40, drawn to a drug delivery device for administering a compound of formulae (I), (VI), (VII), (VII') and (VIII), (a patch), classified in class/subclass 424/449. Further restriction will be required should this Group be elected.

The inventions are distinct, each from the other because:

As evidenced by the different classifications, the compounds set forth in Groups I-X above have acquired a separate status in the art and would require separate searches which are not overlapping. Each one of the Groups set forth in this requirement is not an obvious variant of any other Group herein. So, each group requires a different search of the chemical literature to evaluate the patentability of compounds in that Group.

The compounds falling into the different categories I-X set forth above are patentably distinct as well.

Devices as set forth in Group XI require a separate search of the medical literature than do simple pharmaceutical compositions comprising the compounds. A patch is actually not a composition, it is a device.

The mixed compounds in Group IX will necessitate a search of the chemical literature relating to synthesis of such complexly substituted compounds in order to evaluate compliance with the first paragraph of 35 U.S.C. 112 of claims drawn to such compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

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matter, restriction for examination purposes as indicated is proper. A showing of separate classification is *prima facie* evidence of:

1. Separate classification.
2. Separate status in the art.
3. Different field of search.

Comments

The second through fifth compounds named in instant claim 30, in Group IX above, have already been patented in US 6,713,464, which is the parent of the instant application.

Compounds possessing both ester and ether functions or ester and silylether functions, which are recited in claim 32, do not find antecedent basis in claim 31.

The last named compound in claim 32 also does not find antecedent basis in claim 31.

Claim 38 includes a spelling error, "...carbonates and carbonates..."

Conclusion

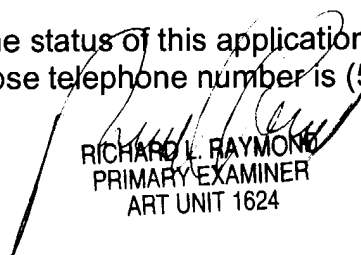
Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday-Friday from 6:30am to 3:00pm. If Attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mukund Shah, can be reached at (571) 272-0674.

If, after a 24-hour period, Dr. Shah is unreachable, contact the examiner's acting supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (703) 308-4556 for regular communications and (703) 308-4242 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-2717.

zt



RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624